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| 10/636,055  | 08/07/2003  | Alonzo C. Aylsworth  | 2230-00400          | 1019             |
| 23505   | 7590        | 12/29/2004           | EXAMINER            |                  |
| CONLEY ROSE, P.C.<br>P. O. BOX 3267<br>HOUSTON, TX 77253-3267 |             |                      | LEWIS, AARON J      |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3743                |                  |

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/636,055

Applicant(s)

AYLSWORTH ET AL.

Examiner

AARON J. LEWIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/04/2004 (AMENDMENT).
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-14 and 35-38 is/are allowed.
- 6) ☒ Claim(s) 15-20, 22-34 and 39-45 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richey, II et al. ('165) in view of Frye et al. ('088).

The difference between Richey, II et al. and claim 23 is a conserver coupled to the regulated therapeutic gas stream, the conserver operable to deliver a bolus of therapeutic gas during inhalation of a patient.

Frye et al. teach a conserver (42) coupled to the regulated therapeutic gas stream, the conserver operable to deliver a bolus of therapeutic gas during inhalation of a patient for the purpose of providing oxygen to a patient upon sensing an inhalation attempt and shutting off oxygen to a patient upon sensing an exhalation attempt (col.5, lines 9-12) thereby preventing wasting of oxygen gas.

It would have been obvious to modify Richey, II et al. to include a conserver coupled to the therapeutic gas stream because it would have provided a means for providing oxygen to a patient upon sensing an inhalation attempt and shutting off oxygen to a patient upon sensing an exhalation attempt thereby preventing wasting of oxygen gas as taught by Frye et al.. Further, cylinder (30) of Richey, II et al. is coupled to the

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compressed therapeutic gas stream fully capable of providing therapeutic gas from the cylinder when the intensifier is not in operation (col.8, lines 7-16).

As to claim 24, Richey, II et al. disclose an oxygen concentrator (10,12) coupled to the compressor (100), the oxygen concentrator operable to provide therapeutic gas to the compressor.

As to claim 25, while Richey, II et al. are not specific as to the particular type of oxygen concentrator, it would have been obvious to substitute any well known type of oxygen concentrator including a pressure swing absorption system as one well known oxygen concentrator for another as an obvious matter of design choice. Inasmuch as no criticality is seen for a pressure swing absorption system, it is submitted that the oxygen concentrator of Richey, II et al. would have functioned as efficiently as a pressure swing absorption system.

As to claim 26, Richey, II et al. disclose a connector (210,300) operable to selectively couple the cylinder to the system.

As to claims 27,28, inasmuch as cylinder (30) of Richey, II et al. is a tank, it constitutes a portable component; moreover, it would have been obvious to designate it either internal or external relative to the overall trans-fill system. The mere use of each of the terms internal and external does not convey a structural distinction as they relate to the relative physical cooperative relationship between cylinder (30) and the overall trans-fill system.

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As to claim 29, cylinder (30) of Richey, II et al. is coupled to the compressed therapeutic gas stream fully capable of providing therapeutic gas from the cylinder when the intensifier is not in operation (col.8, lines 7-16).

As to claim 30, the compressor (22,100) of Richey, II et al. by definition includes an intensifier inasmuch as the compressor increases (i.e. intensifies) the pressure of an incoming stream of gas. Further, compressor (100) increases (i.e. intensifies) the pressure of oxygen gas within tank (500) relative to the pressure of the oxygen gas at the input of the compressor.

3. Claims 18,19,33,34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, Jr. ('630).

As to claims 18 and 19, while Todd, Jr. discloses its sensor to be oxygen specific there is no express disclosure of the particular type of oxygen sensor. It is submitted that it would have been obvious to employ any well known type of oxygen sensor including one which detects oxygen by density as an obvious matter of design choice with no new or unobvious results accruing. Inasmuch as no criticality is seen in an oxygen density sensor, it is submitted that the oxygen sensor of Todd, Jr. would function as well as an oxygen sensor that detects by density.

As to claims 33 and 34, while Todd, Jr. discloses its sensor to be oxygen specific there is no express disclosure of the particular type of oxygen sensor. It is submitted that it would have been obvious to employ any well known type of oxygen sensor including one which detects oxygen by density as an obvious matter of design choice with no new or unobvious results accruing. Inasmuch as no criticality is seen in an

oxygen density sensor, it is submitted that the oxygen sensor of Todd, Jr. would function as well as an oxygen sensor that detects by density.

4. Claims 22 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richey, II et al. ('165) in view of Todd, Jr. ('630).

The difference between Richey, II et al. and claim 22 is setting a volume of the bolus of therapeutic gas based on a sensed setting for a continuous flow of therapeutic gas through a flow meter.

Todd, Jr. teaches setting a volume (via control circuit 22 and col.3, lines 61-64) of the bolus of therapeutic gas based on a sensed setting for a continuous flow of therapeutic gas for the purpose of controlling the delivery of therapeutic gas during at least a portion of a patient's inhalation.

It would have been obvious to modify Richey, II et al. to include setting a volume of a bolus of therapeutic gas because it would have provided a means for controlling the amount of gas being delivered to a patient during at least a portion of inhalation as taught by Todd, Jr..

Claim 40 is substantially equivalent in scope to claim 22 and is included in Richey, II et al. as modified by Todd, Jr. for the reasons set forth above with respect to claim 22.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 31,32,39 are rejected under 35 U.S.C. 102(b) as being anticipated by Richey, II et al. ('165).

As to claim 31, Richey, II et al. as discussed above with respect claim 16, also disclose an apparatus comprising; an intensifier operable to take therapeutic gas at a first pressure and increase the pressure of the therapeutic gas to a second pressure, higher than the first pressure; a fill port fluidly coupled to the therapeutic gas at the second pressure, the fill port operable to selectively couple a cylinder to be filled with therapeutic gas; a gas sense device coupled to the fill port, the gas sense device operable to detect content of gas within the cylinder prior to filling.

As to claim 32, Richey, II et al. disclose the gas sense device further comprises an oxygen-specific sensor (265,360).

As to claim 39, Richey, II et al. disclose a method comprising: compressing (22) a stream of low pressure therapeutic gas provided by an oxygen concentration system or other source of therapeutic gas, the compressing forms a compressed therapeutic gas stream; providing a first portion of the compressed therapeutic gas stream to fill a cylinder (30); and providing a second portion of the compressed therapeutic gas stream (via 230) to a patient as a bolus of therapeutic gas. It is noted that compressor (22) of Richey, II et al. draws a stream of low pressure therapeutic gas from ambient atmosphere which is readable upon "...other source of therapeutic gas...".

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 15-17,20 are rejected under 35 U.S.C. 102(a and e) as being anticipated by Todd, Jr. ('630).

As to claim 15, Todd, Jr. discloses a method comprising: compressing (17,35) a stream of low-pressure therapeutic gas to form a compressed therapeutic gas stream of sufficient pressure to fill a cylinder (18); providing a first portion (38) of the compressed therapeutic gas stream to fill a cylinder (18); and providing a second portion (via regulator 39 and valve 40) of the compressed therapeutic gas stream to a patient in as a bolus of therapeutic gas.

As to claims 16,17 and 19, Todd, Jr. discloses prior to the compressing step and providing steps, testing the gas within the cylinder (col. 5, lines 46-63) for its oxygen concentration. That is, the gas that would fill cylinder (18) is tested prior to filling.



As to claim 20, Todd, Jr. as discussed above with respect to claims 16 and 17, refrains from filling cylinder (18) if the oxygen concentration is below a predetermined threshold which inherently includes the condition in which impurities are sensed.

1. Claims 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, Jr. ('630) in view of Richey, II et al. ('165).

As to claim 41, the difference between Todd, Jr. and claim 41 is a compressor operable to increase pressure of therapeutic gas to create a compressed therapeutic gas stream having sufficient pressure to fill a cylinder.

Richey, II et al. teach a compressor (22), as part of an oxygen concentrator, the compressor operable to increase pressure of therapeutic gas to create a compressed therapeutic gas stream having sufficient pressure to fill a cylinder (30).

Inasmuch as Todd, Jr. discloses an oxygen concentrator (11) for creating a therapeutic gas stream, it would have been obvious to employ any well known oxygen concentrator including one having a compressor as taught by Richey, II et al..

As to claims 42 and 43, Todd, Jr. teaches compressor (17) for compressing the therapeutic gas stream and filling cylinder (18). The particular pressures required for filling cylinder (18) can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular pressures including 40psi and 2200psi. The pressures required to fill cylinder (18) would vary in dependence upon the desired amount of therapeutic gas being stored therein; accordingly, the more breathable gas being stored in cylinder, the higher the pressure required to force the therapeutic gas into the cylinder.

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As to claim 44, Todd, Jr. as modified by Richey, II et al. as discussed above with respect to claim 41 teaches a first compressor (22 of Richey, II et al.) and a second compressor (17,35) of Todd, Jr.. The overall trans-fill system of Todd, Jr. (col.5, line 46-col.6, line 44) as modified by Richey, II et al. is operable to provide therapeutic gas to a cylinder connector (38) for cylinder #18 of Todd, Jr. to fill the portable cylinder (18) while providing therapeutic gas to the patient through the conserver (#14 of Todd, Jr.).

As to claim 45, Todd, Jr. discloses a gas sense device fluidly coupled to the cylinder connector, the gas sense device operable to detect purity of therapeutic gas and wherein the trans-fill system is operable to allow a portion of the gas within a connected portable cylinder to flow to the gas sense device, and wherein the trans-fill system refrains from filling the connected portable cylinder if the purity of the gas in the bottle, as determined by the gas sense device, falls below a predetermined threshold (col.5, lines 46-63).

### ***Claim Objections***

1. Claim 21 is objected to because of the following informalities: the manner of making amendments to claim 21 has resulted in a lack of antecedent basis for the term "...the cylinder..." in lines 2 and 3. Appropriate correction is required.

### ***Allowable Subject Matter***

1. Claims 1-14,35-38 are allowed.

### ***Response to Arguments***

2. Applicant's arguments filed 10/04/2004 have been fully considered but they are not persuasive. As to applicant's arguments regarding claim 15, tank (30) of Richey, II

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et al. contains compressed therapeutic gas from compressor (22). A portion that remains in tank (30) while another portion is provided to a patient as a bolus of breathable gas is readable as a first portion and a second portion, respectively.

As to applicant's arguments regarding claim 23, tank (30) of Richey, II et al. (as discussed above with respect to claim 15) contains compressed therapeutic gas from compressor (22). A portion that remains in tank (30) while another portion is provided to a patient as a bolus of breathable gas is readable as a first portion and a second portion, respectively. Additionally, the system of Richey, II et al. is fully capable of providing therapeutic gas from cylinder (30) when compressor (22) is not in operation inasmuch as therapeutic gas from compressor (22) is temporarily stored in cylinder (30).

As to applicant's arguments regarding claim 31, the fill port of tank/cylinder (200) of Richey, II et al. is fluidly coupled to the therapeutic gas and gas sense device (265) which senses the content of tank/cylinder (200) prior to filling.

### ***Conclusion***

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

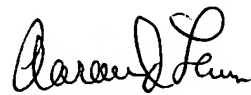
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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
AARON J. LEWIS  
Primary Examiner  
Art Unit 3743

Aaron J. Lewis  
December 23, 2004